



State Agency  
of Medicines  
Republic of Latvia

# EXPERIENCE OF LATVIA ON CONTINGENCY OF PDMPs

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# LATVIA

## Country profile

### Demographic and socioeconomic factors:

- Population 1,873 millions (2024)
- Share of population over age 65 (%) 21 (2024)
- Fertility rate 1,74 (2023)
- GDP per capita (EUR PPP) 71% of EU average

### Blood donation:

- **Donors 1,74 %**
- **FTD 17,7%**
- **Latvian patients get blood components and plasma products free of charge**

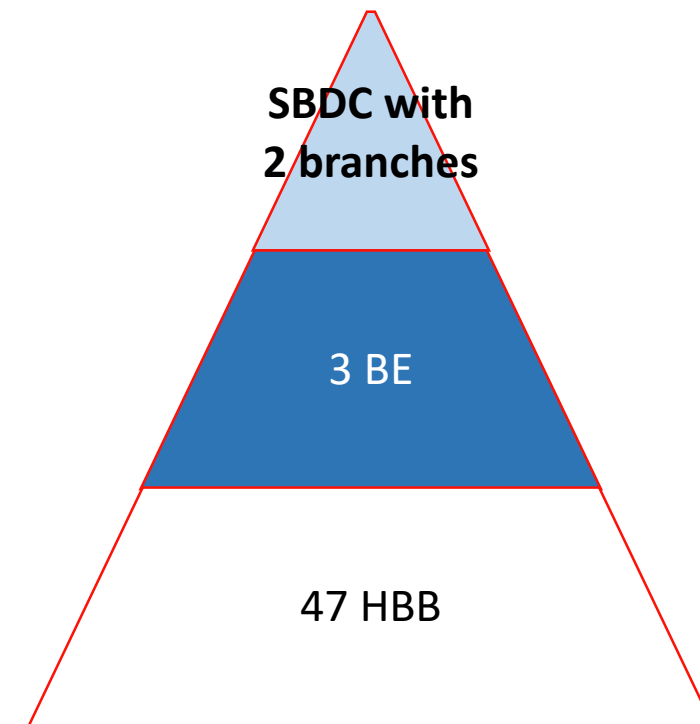
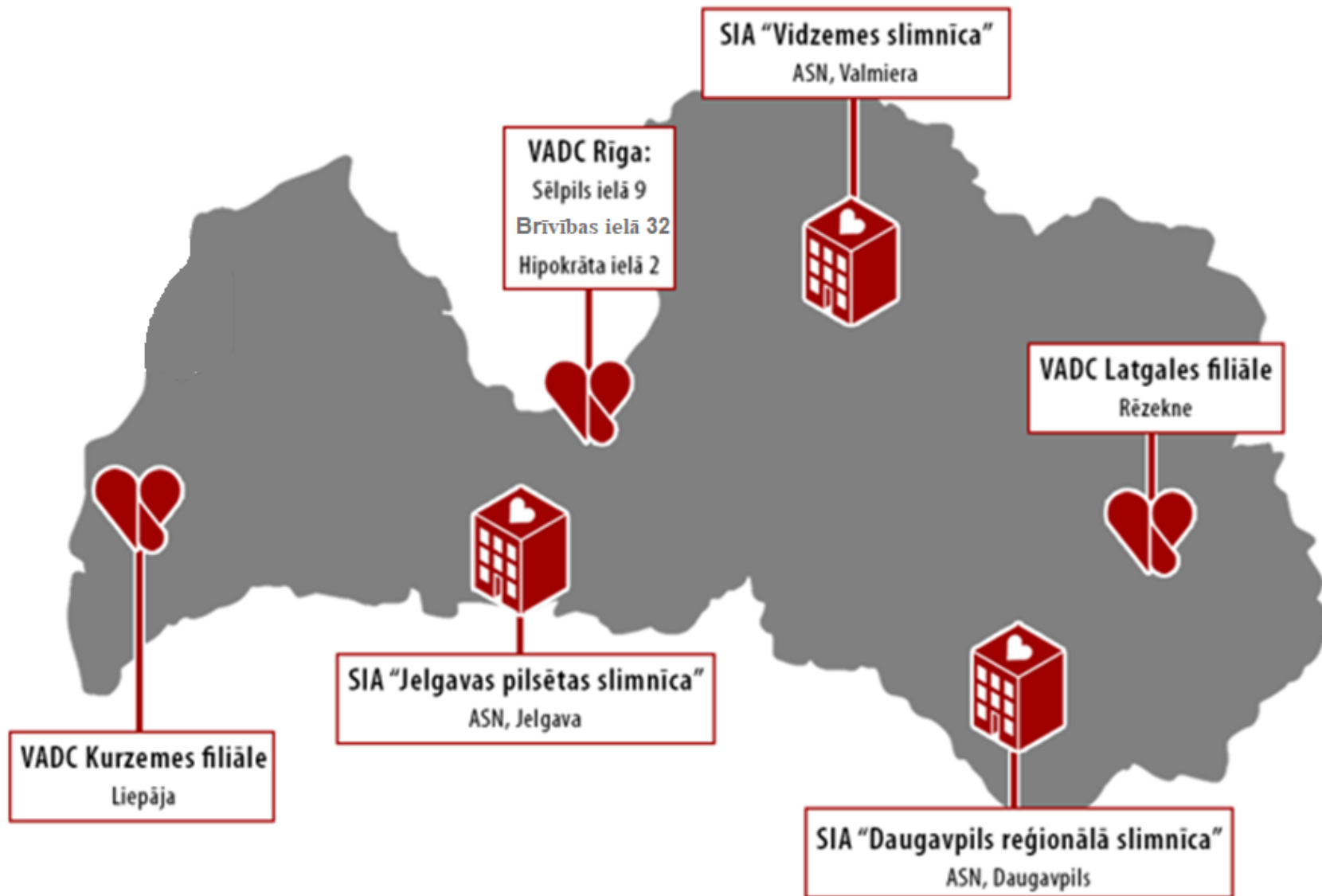


# LATVIA

## SoHO NCAs

- **Ministry of Health**
  - Policy makers
- **State Blood Donor Centre**
  - Blood Service,
  - Qualification and specialization
- **State Agency of Medicines**
  - Authorisation of SoHO entities and establishments
  - Autorisation of MP, HTA and market surveillance
  - Vigilance
- **National Accreditation Bureau**
  - Laboratory standards ISO 17025, ISO 15189
- **Health Inspectorate**
  - Regulatory compliance of HCP
- **Other**

# Structure of Blood Service



# Latvian Blood service

- **State Blood Donor Center (SBDC)**
  - Riga
  - Latgale (in Rezekne)
  - Kurzeme (in Liepaja)
- **3 blood establishments (blood collection departments) at the biggest state hospitals**
  - collect blood and process blood components
- **47 hospital blood banks.**
- **2 mobile buses and 2 buses for «in-house» donations.**

Hospital blood banks take blood components from the blood establishments on request, store them, ensure compatibility testing, issue for transfusion and report to Haemovigilance system.



# DONORS IN 2023.

BLOOD WAS DONATED  
**59 912**  
TIMES

IN TOTAL WE HAD  
**785**  
OUTINGS



FROM THOSE  
**249**  
WERE WITH A BUS



**34 185**  
TOTAL NUMBER OF DONORS

**308**  
DONORS DONATED  
ON THEIR BIRTHDAY



THE PERCENT  
OF DONORS WHO  
DONATED ON OUR OUTINGS  
**50.7% OF DONORS**

THE  
AVERAGE  
AGE OF  
DONORS  
**38** YEARS

AVERAGE AGE  
OF FIRST TIME DONORS  
**31** YEARS OF AGE



**47.2% MEN**



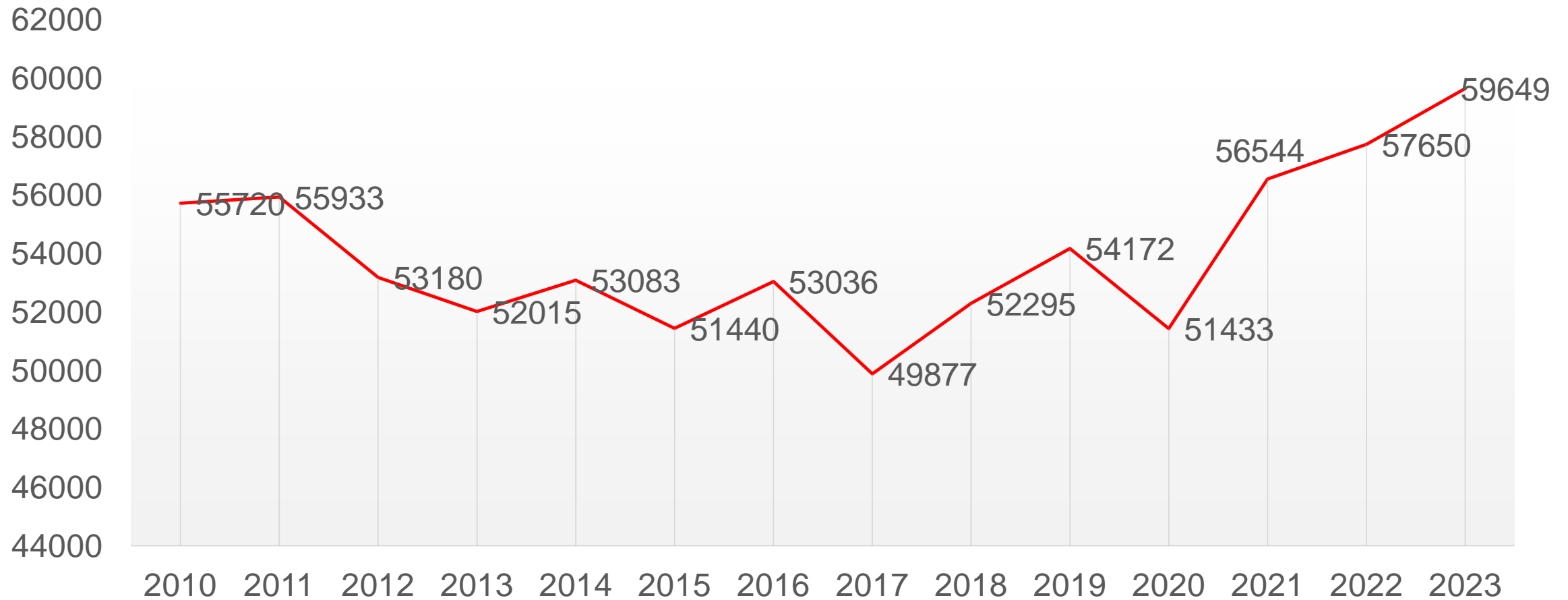
**52.8% WOMEN**

## HOW MANY TIMES DONORS DONATED

**18 590   8 491   4 576   2 057   442   29**



# Blood Donations



7

Cryoprecipitate and cryodepleted plasma 12832 doses

# State Agency of Medicines

Authorisation of medicinal products, CTs, HTA and pharmacovigilance

Licensing of pharma and SoHO operators

Continuous monitoring and information availability, shortages and prices

Response to pandemic and emergencies

Review of legislation and new proposals

EU level participation

- MSSG
- HERA advisory forum
- SPOC network



# PDMPs and humanised MABs sell-out data – Latvia, 2019 - 2023

## Volume of PDMP's

- + humanised MAB - equine BP
- Immunoglobulins **J06B**
- Coagulation factors **B02BD**
- Albumin **B05AA01**

## Distributed authorised PDMPs and humanised MABs

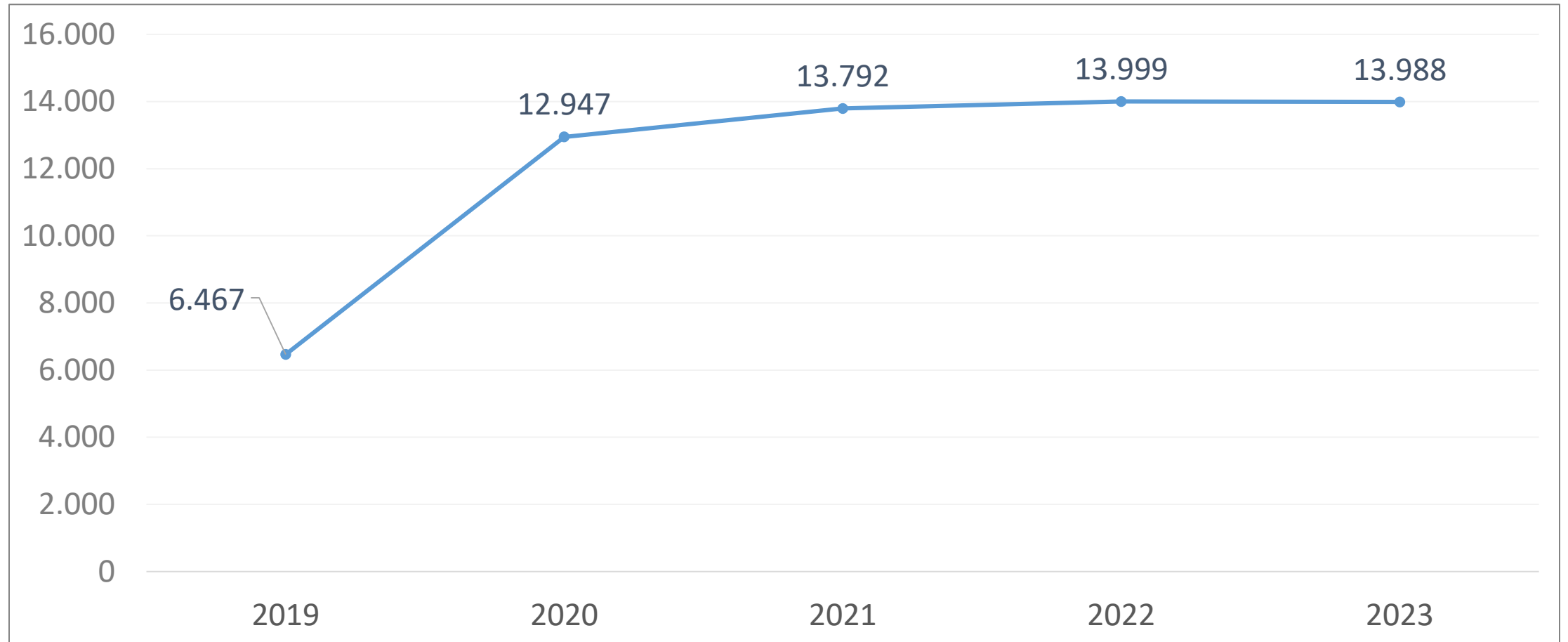
- IGs, normal human, for intravascular adm.
- IGs, normal human, for extravascular adm.
- anti-D (rh) IG
- rabies IG
- hepatitis B IG
- tetanus IG

- Humanised MABs (bezlotoxumab, tixagevimab and cilgavimab, palivizumab)
- albumin
- coagulation factor VIII
- coagulation factor VII
- factor VIII inhibitor bypassing activity
- von willebrand factor and coagulation factor VIII in combination
- coagulation factor IX
- coagulation factor VIIa
- coagulation factor IX, II, VII and X in combination

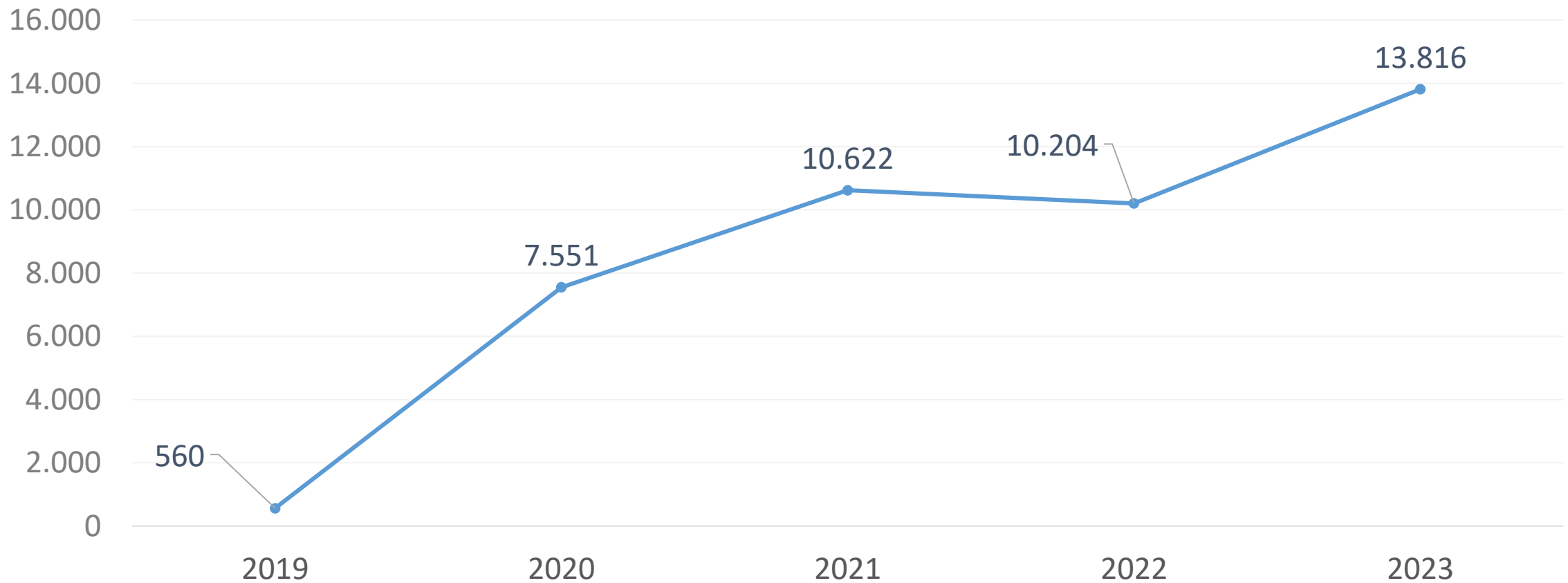
## Distributed unauthorised PDMPs

- Coagulation factor IX, Coagulation factor X, Coagulation factor VII, Protein C, Protein S
- Coagulation factor VIII
- Coagulation factor II, Coagulation factor VII, Coagulation factor IX, Coagulation factor X coagulationis humanus, Protein C
- tetanus IG
- hepatitis B IG
- rabies IG
- anti-D (rh) IG

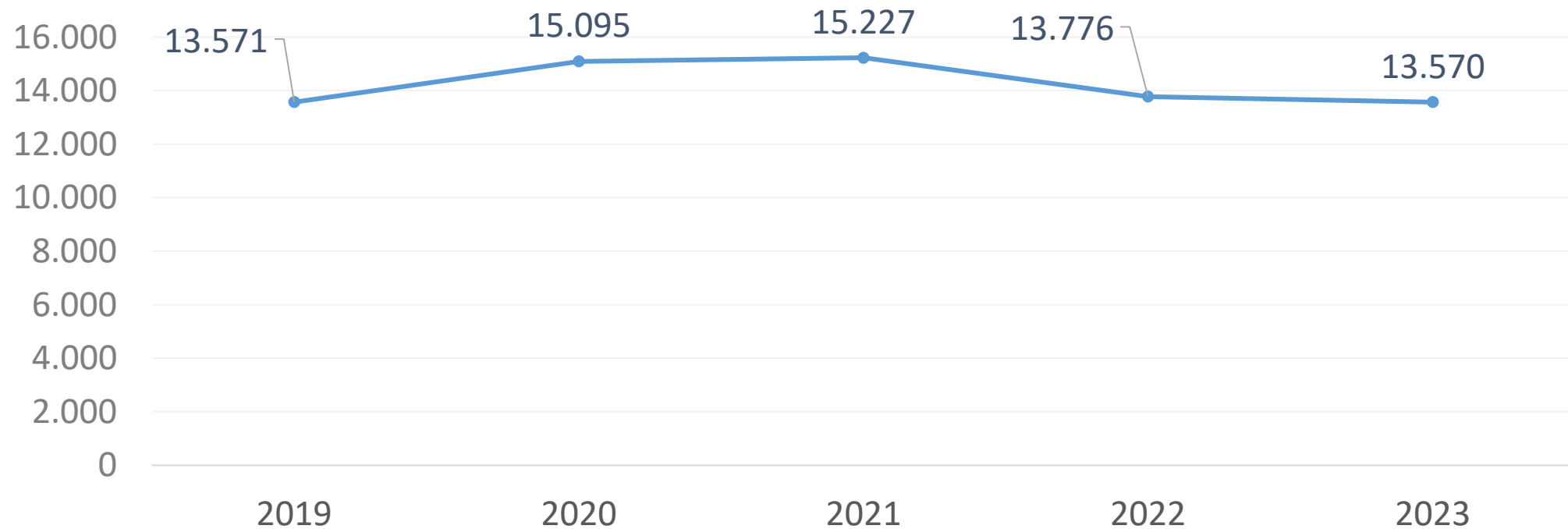
# Immunoglobulins Packages distributed



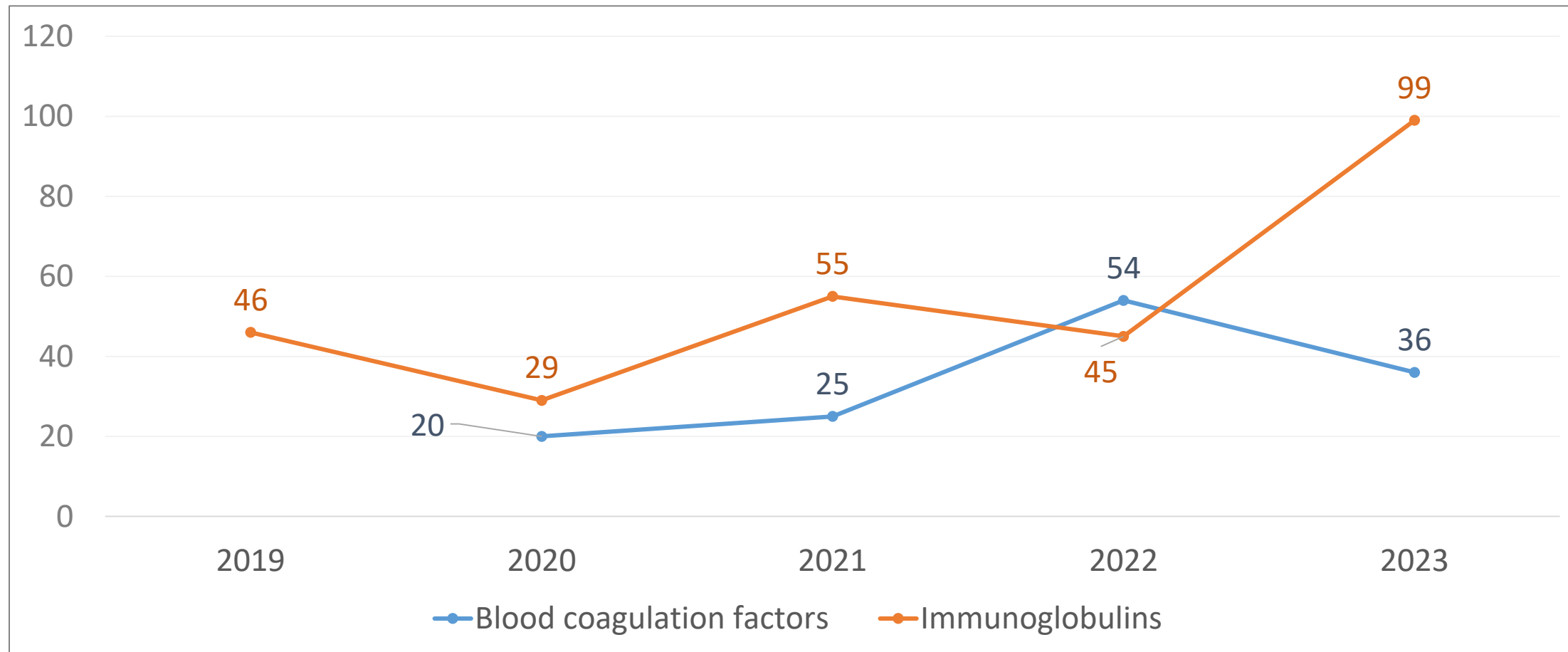
# Albumin Packages distributed



# Blood coagulation factors Packages distributed



# Unauthorised PDMPs Packages distributed



# Challenges and opportunities

Aging and health level  
relating to donation  
activity and quality

Gaps in human resources  
for existing and future  
demands

New SoHO regulation  
(incl. wider scope, portal,  
vigilance, crisis  
preparedness)

New EU Pharmaceutical  
Reform (incl. SPPs and  
SMPs)

Forecasting of routine and  
non-routine demand  
(operational stocks, shelf  
life, crisis preparedness,  
military demand)

ATMPs and ATMPs HEx

«Black Swan»



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